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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/021,294	12/19/2001	Suzie Hwang Pun	038134-5006	9341
28120	7590	07/28/2004	EXAMINER	
ROPE & GRAY LLP ONE INTERNATIONAL PLACE BOSTON, MA 02110-2624			MAIER, LEIGH C	
			ART UNIT	PAPER NUMBER
			1623	
DATE MAILED: 07/28/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/021,294	<b>Applicant(s)</b> PUN ET AL.	
	<b>Examiner</b> Leigh C. Maier	<b>Art Unit</b> 1623	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

**A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.**

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 13 May 2004.  
2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 5-7 and 11-21 is/are pending in the application.  
4a) Of the above claim(s) 20 and 21 is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☒ Claim(s) 5-7 and 11-19 is/are rejected.  
7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.  
10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All    b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 13, 2004 has been entered.

### ***Election/Restrictions***

The claims under prosecution remain subject to an election of species requirement, as set forth previously. The set of species has been expanded to the "guest" molecules set forth in claim 11 with a generic therapeutic agent. Claims 20 and 21 remain withdrawn from consideration as being drawn to a non-elected invention.

### ***Claim Objections***

Claim 19 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim, or amend the claim to place the claim in proper dependent form, or rewrite the claim in independent form. The claim recites "the polymer comprises a host moiety that forms an inclusion complex with a guest moiety." However, this claim depends from claim 5, which requires a cyclodextrin, by definition, a host moiety.

Art Unit: 1623

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 5-7 and 11-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over ZHAO et al (US 6,667,293) and GONZALEZ et al (Bioconj. Chem., 1999).

ZHAO teaches the administration of a composition comprising an adamantane-linked oligonucleotide (complexing agent) and a cyclodextrin for the treatment of pathogenic infections. The reference further suggests additional components, such as other nucleotides and chemotherapeutic drugs (therapeutic agents). The reference does not teach a cyclodextrin-containing polymer. The reference further suggests of other agents to assist in delivery. See col 7-8.

Art Unit: 1623

GONZALEZ teaches the use of cyclodextrin-containing polymers for the delivery of macromolecular therapeutics. The reference specifically suggests delivery of oligonucleotides. See entire reference.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the compositions taught by ZHAO by the use of cyclodextrin-containing polymers taught by GONZALEZ. One of ordinary skill would be motivated to make this modification with a reasonable expectation of success because GONZALEZ had suggested their use in the delivery of oligonucleotides.

Claims 5-7 and 11-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over ZHAO et al (US 6,667,293) and GONZALEZ et al (Bioconj. Chem., 1999) in further view of AMIEL et al (Int. J. Polym. Anal. Char., 1995) or CARPENTER et al (US 4,877,778).

ZHAO and GONZALEZ teach as set forth above. The references do not teach the use of a naphthalene or cholesterol "guest" moiety.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the composition taught by the combination of ZHAO and GONZALEZ by substituting the adamantane moiety with any appropriate entity known to form a complex with a cyclodextrin with a reasonable expectation of success. Naphthalene is taught by AMIEL. See abstract. Cholesterol is taught by CARPENTER. See col 1-2. It would be within the scope of the artisan to make such a modification through routine experimentation.

***Double Patenting***

Claims 5-7 and 11-21 are again provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 17-20 of copending Application No. 10/021,312, as set forth in a previous Office action.

Applicant has indicated a willingness to submit a terminal disclaimer, if necessary, upon notice of allowability.

***Allowable Subject Matter***

Allowable subject matter was indicated in a previous Office action. Upon further searching, the scope of allowable subject matter is expanded to include a composition comprising:

1. a CD-containing polymer;
2. a therapeutic agent; and
3. guest—PEG (optionally including branching and additional linkers)—functional group.

As noted previously, “therapeutic agent,” “guest,” and “functional group” are generic. The art of record teaches as set forth above. The art does not provide any motivation to prepare complexing agents having PEG linkers.


Art Unit: 1623

***Examiner's hours, phone & fax numbers***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leigh Maier whose telephone number is (571) 272-0656. The examiner can normally be reached on Tuesday, Wednesday, and Friday 7:00 to 3:30 (ET).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O. Wilson (571) 272-0661, may be contacted. The fax number for Group 1600, Art Unit 1623 is (703) 872-9306.

Visit the U.S. PTO's site on the World Wide Web at <http://www.uspto.gov>. This site contains lots of valuable information including the latest PTO fees, downloadable forms, basic search capabilities and much more.



Leigh C. Maier  
Patent Examiner  
July 22, 2004